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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,619	07/27/1999	SHEENA M. LOOSMORE	1038-921-MIS	5733

7590

03/26/2003

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/361,619

Applicant(s)
Loosemore et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-10 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 9, and 10 ~~is~~/are rejected.
- 7) ☒ Claim(s) 7 and 8 ~~is~~/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 01/03/03 (paper no. 17) in response to the Office Action mailed 07/01/02 (paper no. 16).

Status of Claims

- 2) Claims 3 and 4 have been canceled via the amendment filed 01/03/03.
Claims 1, 2 and 5 have been amended via the amendment filed 01/03/03.
Claims 1, 2 and 5-10 are currently under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 5) The objection to the drawings made in paragraph 7 of the Office Action mailed 09/25/01 (paper no. 14) is maintained for reasons set forth therein and in paragraph 5 of the Office Action mailed 07/01/02 (paper no. 16).

Rejection(s) Withdrawn

- 6) The rejection of claim 2 maintained in paragraph 10 of the Office Action mailed 07/01/02 (paper no. 16) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 7) The rejection of claims 7 and 8 made in paragraph 12 of the Office Action mailed 09/25/01 (paper no. 14) and maintained in paragraph 12 of the Office Action mailed 07/01/02 (paper no. 16) under 35 U.S.C § 112, first paragraph, as being non-enabled, with regard to the deposit issue, is withdrawn.

Applicants state the following at paragraph 6 on page 4 of the amendment filed 01/03/03:

It is **already stated**, under the signature of the undersigned that all restrictions to public access to the

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deposits will be **irrevocably removed** upon the grant of a patent on this application. [Emphasis added].

However, it is noted that the statement made at first paragraph on page 8 of the amendment filed 03/25/02 stated the following:

It is hereby stated, under the signature of the undersigned, that all restrictions to public access to the deposits will be **removed** upon the grant of a patent on this application and that

Although the term 'irrevocably' was not a part of the statement made on page 8 of the amendment filed 03/25/02, the current response is considered sufficient to obviate the rejection.

8) The rejection of claims 1, 5-7, 9 and 10 made in paragraph 18 of the Office Action mailed 07/01/02 (paper no. 16) under 35 U.S.C § 102(e) as being anticipated by Loosmore *et al.* (US 6,391,313), is withdrawn.

9) The rejection of claims 1, 5, 6, 9 and 10 made in paragraph 19 of the Office Action mailed 07/01/02 (paper no. 16) under 35 U.S.C § 102(b) as being anticipated by Sasaki *et al.* (WO 96/34960 - Applicants' IDS), is withdrawn in light of Applicants' amendments to the claims and/or the base claim.

10) The rejection of claims 7 and 8 made in paragraph 15 of the Office Action mailed 07/01/02 (paper no. 16), with regard to part(c) of claim 1, under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn.

Rejection(s) Maintained

11) The rejection of claim 9 made in paragraph 11(b) of the Office Action mailed 09/25/01 (paper no. 14) and maintained in paragraph 11 of the Office Action mailed 07/01/02 (paper no. 16) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants contend that a C-terminal fragment of the 200 kDa protein is clearly described in Example 15 and that a person skilled in the art would understand from this description the meaning of the terminology made in claim 9.

Applicants' arguments have been considered, but are non-persuasive. Applicants are correct that Example 15 describes 'the carboxyl half' of the 200 kDa protein of a strain of *Moraxella catarrhalis*. However, this description does not render the confusing or vague claim language "an approximately C-terminal half". What exactly is encompassed in the term 'approximately' cannot be

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envisioned, because it is not clear what part of the non-C-terminal half of the protein is included in this 'approximately C-terminal half', or what part of the C-terminal portion of the protein is excluded in this 'approximately C-terminal half'. The rejection stands.

12) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 14 of the Office Action mailed 09/25/01 (paper no. 14) and maintained in paragraph 13 of the Office Action mailed 07/01/02 (paper no. 16), with regard to part(c) of claim 1, under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 5,808,024 - Applicants' IDS), is maintained for reasons set forth therein and herebelow.

Applicants contend that claim 1 includes only strain 4223, Q8 and LES-1 and those having a nucleotide sequence having the characteristics of part (c). Applicants state that excluded from claim 1 are strains of *Moraxella catarrhalis* which do not have these characteristics. Applicants submit that they have amended claim 1 to address the use of the term 'having'. Applicants assert that Sasaki *et al.* ('024) do not describe any nucleotide sequence which is the same as SEQ ID NO: 6 as stated in part 1(a) or the fully complementary sequence thereto. With regard to part (c) of claim 1, Applicants state that part (c) requires that the nucleotide sequence encode an about 200 kDa outer membrane protein of another strain of *Moraxella catarrhalis* as recited. Applicants acknowledge that the Office is correct in that the brief description of Figure 6 of the '024 patent states that the nucleotide sequence of the gene has an open reading frame of the 200 kDa outer membrane protein of *Moraxella catarrhalis*. Applicants state that the Figure does not identify such open reading frame. Applicants state that a copy of Figure 6 with ATG and GGG nucleotides highlighted in yellow and indicated to be attached to the Office Action mailed 07/01/02 was not attached to the Office Action.

Applicants' arguments have been carefully considered, but are not persuasive. A copy of Figure 6 of Sasaki *et al.* ('024) with ATG and GGG areas boxed and highlighted in colors is re-supplied along with this Office Action. It should be noted that the nucleotide sequence of SEQ ID NO: 6 recited in part (a) of claim 1 is the species that was elected by Applicants. Part (b) of claim 1 encompasses non-elected species. Claim 1 does not identify 'a strain of *Moraxella catarrhalis*' or 'another strain of *Moraxella catarrhalis*' by a strain number or strain designation. Unlike the nucleotide sequence claimed in claim 1(a), the nucleotide sequence claimed in claim 1(c) is not structurally defined or identified by a SEQ ID number. The recitation 'another strain of *Moraxella*

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catarrhalis does not exclude any specific strain of *Moraxella catarrhalis* via this limitation. Part(c) of claim 1 does not recite any amino acid sequence or any reference SEQ ID number of an amino acid sequence. The limitation 'open reading frame' does not appear in claim 1. The claim language 'amino acids 25 and 35 encoded by the nucleotide sequence' is ambiguous. Claim 1(c) does not recite any reference SEQ ID NO. with an indication of where exactly the residue numbering should start from and where exactly amino acids 25 and 35 are in an amino acid sequence that is currently unidentified in part(c) of the claim. It should further be noted that the GGG tract is a part of the claimed nucleotide sequence and has to be 'located' in the nucleotide sequence, as opposed to an amino acid sequence. As presented currently, the nucleotide sequence claimed in part (c) of claim 1 is required to encode an about 200 kDa outer membrane protein of 'a' strain of *Moraxella catarrhalis* and has to have a GGG, or GGGGGG etc. tract; an ATG codon 'about' 80-90 bp upstream of the tract. The prior art nucleotide sequence structurally meets the nucleotide sequence claimed in part (c) of claim 1, because it does encode an about 200 kDa outer membrane protein of 'a' strain of *Moraxella catarrhalis* and does have: (a) one GGG tract about 102 bp upstream of the tract (i.e., about 90 bp upstream of the tract) and an ATG codon structure at one portion of the sequence as indicated with yellow highlighter in the attached Figure 6 of Sasaki *et al.* ('024), or, (b) a second GGG tract about 86 bp upstream of the tract (i.e., about 80, or about 90 bp upstream of the tract) and an ATG codon structure at a second portion of the sequence as indicated with pink highlighter in the attached Figure 6 of Sasaki *et al.* ('024); or, (c) a third GGG tract about 74 bp upstream of the tract (i.e., about 80 bp upstream of the tract) and an ATG codon structure at a third portion of the sequence as indicated with blue highlighter in the attached Figure 6 of Sasaki *et al.* ('024). The prior art patent '024 does not exclude these ATG codons as start codons. The rejection stands.

13) The rejection of claims 1, 2 and 5, 6, 9 and 10 made in paragraph 15 of the Office Action mailed 07/01/02 (paper no. 16), with regard to part(c) of claim 1, under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicants contend that the rejection is difficult to answer because the 'certain strains' are not identified in the Office Action. Applicants acknowledge that the rejection was directed to the

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nucleic acid molecule recited in part (c) of claim 1 (see fourth paragraph on page 7 of their amendment filed 01/03/03), yet state that parts (a) and (b) of claim 1 define the SEQ ID numbers of strains 4223, Q8 and LES-1. Applicants submit that part 9(c) defines a nucleotide sequence which encodes an about 200 kDa outer membrane protein of another strain, i.e., "other than 4223, Q8 and LES-1" as recited. Applicants state that Table 1A strains strongly express the 200 kDa protein and meet these criteria, and that Table 5 suggests that 'the number of G nucleotides in the G tract are as a regulator of expression'. Applicants conclude that claims 1, 2, 5 and 10 are fully enabled.

Applicants' arguments have been carefully considered, but are not persuasive. Contrary to Applicants' contention, the Office Action did exemplify certain strains of *Moraxella catarrhalis* in the last line on page 7 of the Office Action mailed 07/01/02. Claim 1 does not identify 'a strain of *Moraxella catarrhalis*' or 'another strain of *Moraxella catarrhalis*' by a strain number or a strain designation. Claim 1 does not include the recitation: "other than 4223, Q8 and LES-1". Unlike the nucleotide sequence claimed in claim 1(a), the nucleotide sequence claimed in claim 1(c) is not structurally defined or identified by a SEQ ID number. The recitation 'another strain of *Moraxella catarrhalis*' does not exclude any specific strain of *Moraxella catarrhalis* via this limitation. As set forth in paragraph 15 of the Office Action mailed 07/01/02 (paper no. 16), Table 1A, currently recited in claim 2, lists many strains of *M. catarrhalis*, about 79 of which are indicated in the right column of the Table to be expressers of the 200 kDa protein. The nucleotide sequences of all these 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A, except 4223, Q8 and LES-1, are encompassed in the scope of the claims, which are required to have a G tract of 3 or a multiple of 3 consecutive G nucleotides and an ATG start codon about 80 to 90 bp upstream of the G tract as recited in part(c) of claim 1. However, there is no evidence within the instant specification that these about seventy nine 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A do indeed carry a nucleotide sequence with the recited structural properties. There is neither any evidence, nor is it predictable that nucleic acid molecules from these many strains have the structural characteristics as recited in part(c) of claim 1, and that these were indeed isolated, purified, genetically analysed and were found to have the recited characteristics. There is no showing that 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A, other than strains 4223, Q8 and LES-1, contain a nucleotide sequence that carries a G tract of 3 or a multiple of 3 consecutive G nucleotides and an ATG start

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codon about 80 to 90 bp upstream of the G tract as recited in part(c) of claim 1. Table 5 does not exclude the three (+++) 200 kDa protein-producing strains of *M. catarrhalis* to be strains 4223, Q8 and LES-1, nor does it identify these strains to be strains other than 4223, Q8 and LES-1. Except strains 4223, Q8 and LES-1, the rest of the 200 kDa protein-producing strains listed in Table 1A could as well be containing a nucleotide sequence carrying a G tract of ten consecutive G nucleotides, since ten G-containing strains also produce the 200 kDa protein. Other than the nucleotide sequences from strains 4223, Q8 and LES-1 of *M. catarrhalis*, it appears that Applicants did not have possession, at the time of the invention, of nucleotide sequences from any other strains of *M. catarrhalis* having the characteristics as recited in part(c) of claim 1. The full scope of the instant claims is viewed as being non-enabled. Since the observation obtained from the genetic analysis regarding one strain of *M. catarrhalis* that expresses the 200 kDa protein cannot be extrapolated to every other 200 kDa protein-expressing strain of *M. catarrhalis* with regard to the number of G nucleotides in a G tract, undue experimentation would have been required to practice the full scope of the claims. The rejection stands.

Double Patenting Rejection(s)

14) In paragraph 3 on page 7 of the amendment filed 01/03/03, Applicants stated that no action is required with respect to the double patenting rejection made therein, because the claims of 08/945,567 have **not** been patented. However, this statement is not accurate. The application S.N. 08/945,567 was in fact issued as US patent 6,448,386 on 09/10/02. The instant rejection is necessitated by the issue of the claims of S.N. 08/945,567 and/or Applicants' failure to take necessary action to address the issue.

Claims 1, 2, 5, 6, 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 3-7, 9 and 10 of the US patent 6,448,386 ('386). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claim(s), because the examined claims are either anticipated by, or would have been obvious over, the reference claim(s). The nucleic acid molecule having the DNA sequence of SEQ ID NO: 2, a vector and a host cell comprising the same of the US patent 6,448,386 ('386) anticipate the instant claims. The portion of the U.S. patent 6,448,386 that supports the description of SEQ ID NO: 2 in columns

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41-46, Figure 6 and lines 54-61 in column 6 disclosed a nucleotide sequence as recited in part(c) of instant claim 1, which encodes an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and is characterized by a GGG tract at base positions 555-557 of SEQ ID NO: 2 (i.e., located between amino acids 25 and 35 encoded by the nucleotide sequence) and an ATG start codon about 74 (i.e., about 80) bp upstream of the said GGG tract at base positions 478-480 of SEQ ID NO: 2 (see columns 41 and 42; and lines 54-61 of column 6). The portion of the U.S. patent 6,448,386 that supports the description of the nucleic acid molecule in paragraph 6 of column 2 disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains.

15) Claims 1, 2, 5, 6, 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 5-13 of US patent 5,808,024. These claims of the '024 patent disclosed the nucleotide sequence, SEQ ID NO: 1, or the complementary sequence thereto, a vector and a host cell comprising the same. The portions of the U.S. patent 5,808,024 that support the description of the nucleotide sequence of SEQ ID NO: 1 in Figure 6; lines 30-33 and 59-62 in column 6; and under 'Sequence Listing', disclosed a nucleotide sequence as recited in part(c) of instant claim 1, which encodes an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and is characterized by a GGG tract at base positions 1262-1264 of SEQ ID NO: 1 (i.e., located between amino acids 25 and 35 encoded by the nucleotide sequence) and an ATG codon about 74 (i.e., about 80) bp upstream of the said GGG tract at base positions 1185-1187 of SEQ ID NO: 1 (see columns 21 and 22; and Figure 6, including the marked-up copy provided herein with highlighted areas). The portion of the U.S. patent 5,808,024 that supports the description of the nucleic acid molecule in paragraph 5 of column 2 disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains.

Rejection(s) under 35 U.S.C § 102

16) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C § 102(b) as being anticipated by Sasaki *et al.* (WO 96/34960 - already of record) ('960).

Sasaki *et al.* ('960) disclosed an isolated and purified nucleic acid molecule having a nucleotide sequence encoding a 200 kD outer membrane protein of a strain of *M. catarrhalis* (see claims 14-23 and Figure 6). A plasmid or an expression vector for transforming a host comprising the nucleic acid molecule wherein the host cell is *E. coli* is taught (see abstract, page 28; and claims

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14-23). Sasaki's ('960) nucleotide sequence anticipates the nucleotide sequence claimed in part (c) of claim 1, because it is characterized by a tract of consecutive G nucleotides (i.e., GGG), an ATG start codon 74 (i.e., about 80) bp upstream of said tract, being located between amino acids 25 and 35 of the amino acid sequence of SEQ ID NO: 4 encoded by the nucleotide sequence disclosed by Sasaki's ('960). See fourth full paragraph on page 12 and Figure 6, especially the areas boxed and highlighted in yellow on '11/47' page of Figure 6. The start ATG codon indicated in bold letters by Sasaki *et al.* ('960) on page '11/47' of Figure 6 and the GGG tract located between amino acids 25 and 35 of the amino acid sequence of SEQ ID NO: 4 are boxed and highlighted in yellow in the copy of Sasaki's ('960) Figure 6 attached hereto. Sasaki *et al.* ('960) expressly identified this ATG as the start codon in SEQ ID NO: 4 (see paragraph 4 on page 12). Sasaki *et al.* ('960) also disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains (see paragraph 1 of page 4).

Claims 1, 2, 5, 6, 9 and 10 are anticipated by Sasaki *et al.* ('960).

17) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 6,448,386) ('386).

Sasaki *et al.* ('386) disclosed a nucleotide sequence, SEQ ID NO: 1 or SEQ ID NO: 2, a vector comprising the same and an *E. coli* host cell transformed by said vector, wherein the nucleotide sequence encodes an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and is characterized by a GGG tract at base positions 555-557 of SEQ ID NO: 2 and an ATG codon about 74 (i.e., about 80) bp upstream of the said GGG tract at base positions 478-480 of SEQ ID NO: 2. The nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains (see columns 27-46, especially columns 41 and 42; claims; paragraph 6 in column 2 through paragraph 3 in column 3). That the GGG tract is located between amino acids 25 and 35 encoded by the nucleotide sequence is evident from the amino acid sequence of SEQ ID NO: 4 depicted in columns 55-64, especially columns 55 and 56, and that the ATG codon is the start codon is disclosed in lines 54-61 of column 6. Sasaki *et al.* ('386) disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains (see paragraph 6 of column 2).

Claims 1, 2, 5, 6, 9 and 10 are anticipated by Sasaki *et al.* ('386).

18) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C § 102(e) as being anticipated by

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Sasaki *et al.* (US 6,440,425) ('425).

Sasaki *et al.* ('425) disclosed a nucleotide sequence, SEQ ID NO: 1 or SEQ ID NO: 2, a vector comprising the same and an *E. coli* host cell transformed by said vector, wherein the nucleotide sequence encodes an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and is characterized by a GGG tract at base positions 555-557 of SEQ ID NO: 2 and an ATG codon about 74 (i.e., about 80) bp upstream of the said GGG tract at base positions 478-480 of SEQ ID NO: 2. The nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains (see columns 27-46, especially columns 41 and 42; and paragraph 6 in column 2 through paragraph 3 in column 3). That the GGG tract is located between amino acids 25 and 35 encoded by the nucleotide sequence is evident from the amino acid sequence of SEQ ID NO: 4 depicted in columns 55-64, especially columns 55 and 56, and that the ATG codon is the start codon is disclosed in the last paragraph of column 6. Sasaki *et al.* ('425) disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains (see paragraph 6 of column 2).

Claims 1, 2, 5, 6, 9 and 10 are anticipated by Sasaki *et al.* ('425).

Prior Art

19) The prior art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Sasaki *et al.* (US 6,440,424 and US 6,335,018) disclosed the nucleotide sequence, SEQ ID NO: 1, or the complementary sequence thereto, a vector and a host cell comprising the same. The portions of these U.S. patents that support the description of the nucleotide sequence of SEQ ID NO: 1 in Figure 6; last half of column 2; and under 'Sequence Listing' in columns 21-28; paragraph bridging columns 2 and 3; and second and third paragraphs in column 3, disclosed a nucleotide sequence as recited in part(c) of instant claim 1, which encodes an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and is characterized by a GGG tract at base positions 1262-1264 of SEQ ID NO: 1 (i.e., located between amino acids 25 and 35 encoded by the nucleotide sequence) and an ATG codon about 74 bp upstream of the said GGG tract at base positions 1185-1187 of SEQ ID NO: 1 (see columns 21 and 22; and Figure 6B and 6C). The portion of these US patents that supports the description of the nucleic acid molecule in paragraph 5 of column 2 disclosed that the nucleic acid is from *Moraxella catarrhalis* strain 4223, or other strains.

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Remarks

20) Claims 1, 2, 5, 6, 9 and 10 stand rejected. Claims 7 and 8 are objected to as being dependent from a rejected claim.

21) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

22) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER